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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/406,473	09/27/1999	STEPHEN D. PACETTI	50623-00008	1646

7590 09/07/2006  
CAMERON KERRIGAN  
SQUIRE, SANDERS & DEMPSEY LLP  
ONE MARTINE PLAZA  
SUITE 300  
SAN FRANCISCO, CA 94111-3492

EXAMINER
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THANH, LOAN H

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/406,473	<b>Applicant(s)</b> PACETTI, STEPHEN D.	
	<b>Examiner</b> LoAn H. Thanh	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 April 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 139-154 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 139-154 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 139-154 are rejected under 35 U.S.C. 103(a) as obvious over Sahatjian et al. (U.S. Patent No. 5,674,192).

Sahatjian et al. disclose the invention substantially as claimed. Sahatjian et al. disclose a medical kit comprising a coated stent deployed by a balloon catheter wherein the stent is coated with a therapeutic substance. Further, it is disclosed that the sheath is made of polyurethane or TEFLON (fluorinated polymer). Sahatjian et al. teach the sheath is for protecting the drug/coating and for inhibiting premature release of the drug. The protective sheath is for preventing the release of the drug prior to reaching the desired location in the body. See col. 1-3, 8, 10-11, and 14. The Examiner is taking the position that it is inherent that the polyurethane has a glass transition temperature (T<sub>g</sub>) that is above storage temperature. In the broadest interpretation the storage temperature has not been specified, thus the temperature can be any temperature. Further, it would be inherent for the T<sub>g</sub> to be above storage temperature since the sheath would be a solid structure. If the T<sub>g</sub> were below the storage temperature then the sheath would be a liquid or unstable form during storage. It is inherent that the

Art Unit: 3763

materials of the Sahatjian have the oxygen transmission rate as evidenced by Marotta (Packaging Forum) and further all materials have a water vapor transmission rate.

However, Sahatjian et al. does not disclose the non-polar soft segment to be hydrocarbons or silicones or fluorosilicons or mixtures thereof. It is common knowledge in the chemical art to modify the non-polar segments in order to provide properties such as flexibility and bendability which are desired in the medical arts. In absence of convincing objective evidence to the contrary, it would have been obvious to modify any medically acceptable material to the essential properties, which are desired.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Further it would have been obvious design choice lacking any criticality or unexpected results to modify the water vapor transmission rate as claimed. Properties of the material are easily modified in order to obtain through routine experimentation in determining optimum results. However these parameters are deemed matters of design choice well within the general skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Further, applicant's specification has disclosed suitable combinations of barrier polymers and therapeutic substances but has also disclosed that other suitable combinations are possible. Applicant has also disclosed that in the broader aspects of

Art Unit: 3763

the invention the sheath may not be in contact with the therapeutic agent and thus the therapeutic substance would not absorb or diffuse into the sheath material.

Applicant is suggested to show or provide criticality or unexpected results of the claimed properties of these materials.

### ***Response to Arguments***

Applicant's arguments filed 04/25/06 have been fully considered but they are not moot in view of the new rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 09/406,473

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LoAn H. Thanh  
Primary Examiner  
Art Unit 3763

LT  
09/05/06